Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Enalapril (heart failure, from birth to ≤ 17 years) (repeal of the resolution of 15 August 2024)

of 7 November 2024

At its session on 7 November 2024, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. The findings on the benefit assessment of the active ingredient enalapril in the therapeutic indication according to the marketing authorisation of 15 November 2023, for the treatment of heart failure in children from birth to less than 18 years, in Annex XII to the Pharmaceuticals Directive in the version of the resolution of 15 August 2024 (BAnz AT 17.09.2024 B2) are repealed.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 7 November 2024.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 7 November 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken